DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD

AUG 2 2002

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Ms. Kathy Wilson
Manager Formulations,
Specifications & Regulatory Affairs
Parmalat Canada Bakery Division
Post Office Box 9052
135 Otonabee Drive
Kitchener, Ontario N2G 4J3

Re: 21 CFR 130.17(i) - Participation in Extended Temporary Marketing Test of "White Chocolate" under Docket No. 93P-0310

Dear Ms. Wilson:

This is to acknowledge your letters of March 8, 2002, July 12, 2002, and July 25, 2002, notifying the Food and Drug Administration (FDA) of your acceptance of the invitation, set forth in the FEDERAL REGISTER of December 29, 1994 (59 FR 67302; Docket No. 93P-0310), to participate in the extended temporary market testing of "white chocolate" under the conditions published in the notice. Previously in a letter dated October 1, 1999, FDA granted a permit to Parmalat Canada Bakery Division to participate in the extended temporary market testing of white chocolate under Docket No. 93P-0310. That permit allowed for the market testing of products named "Parmalat Bed and Breakfast White Chocolate Chunk and Macadamia Cookies." The permit was amended on April 21, 2001, to provide for an additional 19,000 kilograms (42,000 pounds) of another white chocolate product. FDA is granting a further amendment to the permit of October 1, 1999, to provide for the market test of another white chocolate product. The product will bear the name "Bayberry Farms White Chocolate Chip Macadamia Cookies" and will be sold in 12 ounce (340 grams) packages.

The test product "Bayberry Farms White Chocolate Chip Macadamia Cookies" contains a component, identified as "white chocolate" that deviates from the U.S. standards of identity for certain chocolate products, i.e., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 163.123), milk chocolate (21 CFR 163.130), buttermilk chocolate (21 CFR 163.135), skim milk chocolate (21 CFR 163.140), or mixed dairy product chocolates (21 CFR 163.145). The white chocolate component differs from the standardized chocolate products in that: (1) it is prepared without the nonfat components of the ground cacao nibs, but contains the fat (cocoa butter) expressed from the ground cacao nibs; and (2) it may contain safe and suitable antioxidants. In all other respects, the white chocolate component would conform to the cacao product standards.

White chocolate, as defined under the extended permit, is the solid or semi-plastic food prepared by intimately mixing and grinding cocoa butter with one or more nutritive carbohydrate sweeteners and one or more of the optional dairy ingredients specified in part 163. It contains not less than 20 percent of cocoa butter, not less than 14 percent of total milk

93P-0310 LET 102

solids, not less than 3.5 percent of milkfat and not more than 55 percent of nutritive carbohydrate sweetener. It may also contain emulsifying agents, spices, natural and artificial flavorings and other seasonings, and antioxidants approved for food use. It contains no coloring material.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of 10,000 kilograms (22,000 pounds) annually of the new test product. The product will be manufactured at Colonial Cookies, 135 Otonabee Drive, Kitchener ON N2G 4J3 for Spartan Stores of Grand Rapids, Michigan, and will be distributed in Indiana, Michigan, and Ohio.

The draft label that you submitted for the test food is acceptable for the purpose of this market test. A finished label must be submitted to the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-822), before the product is shipped in interstate commerce. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR Part 101.

While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of "white chocolate" covered by this permit on the grounds that the food fails to comply with the standards of identity for certain chocolate products, e.g., chocolate liquor (21 CFR 163.111), sweet chocolate (21 CFR 163.123), milk chocolate (21 CFR 163.130), buttermilk chocolate (21 CFR 163.135), skim milk chocolate (21 CFR 163.140), or mixed dairy product chocolates (21 CFR 163.145).

Sincerely yours,

Christine L. Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

parmalat
CANADA

Bakery Division

March 8, 2002

Chief of the Food Standards Branch
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park MD 20740-3835

Dear Sir or Madam,

Re: Bayberry Farms White Chocolate Chip Macadamia Cookies 12 oz (340g)

Enclosed please find a draft label of the above-named products for which we are requesting permission to conduct a test market.

This product will be manufactured at our plant, Colonial Cookies, 135 Otonabee Drive, Kitchener ON N2G 4J3 (800) 265-6508 for Spartan Stores of Grand Rapids MI.

The cookies consist of white chocolate chips and macadamia nuts in a buttery cookie base. Each cookie contains approximately 24% white chocolate. In accordance with CFR section 130.17.(c)(3), the white chocolate is in compliance with the proposed white chocolate standard published in the Federal Register/Vol.62, No. 46, Monday March 10, 1997, Docket Nos. 86P-0297 and 93P-0091. A copy of the product specification has been enclosed for your reference.

We plan to distribute about 10,000 cases annually of 12 x 12 oz of this product. The products will be sold in Michigan, Ohio and Indiana.

At 24% of the finished product, we will be distributing about 22,000 lb (10,000 kg) of white chocolate.

We appreciate your early attention to this matter. Please contact us if you require any further information.

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P.O. Box 9052, 135 Otonabee Drive, Kitchener, Ontario N2G 4J3 Tel: (519) 893-6400 Fax: (519) 893-9223
A Division of Parmalat Dairy and Bakery Inc.

Kind regards,

K Wilson

Kathy Wilson
Manager Formulations, Specifications & Regulatory Affairs

Encl.

1158

BARRY CALLEBAUT

CANADA

PRODUCT SPECIFICATION (Tentative)

This tentative specification is currently under review. Therefore its contents is subject to change.

Description : Ultimate White Chocolate Chips - 2M
Weight / unit : 50 lbs
Units / pallet : 40 cases
Kosher Certification : Ⓚ D

Item No: 70-084
Style : Chips
Form: N/A
Size: 2,000 ct/lb

Ingredients: Sugar, cocoa butter, whole milk powder, skim milk powder, butterfat, soya lecithin (added as an emulsifier), vanilla extract

Chemistry and Physical Characteristics :

	Criteria	Method
Size	2,000 ± 100 ct/lb	MML 1041 (Weight Of 100 Pieces)
Fat Content	27.8 ± 1.0%	MML 1001 (NMR)
Moisture	1.0% Max	MML 1011 (Near Infra-Red)
Particle Size	85% < 29µ	MML 1006 (Laser Diffraction)
Viscosity	N/A	

Microbiology :

	n	c	m	M	Method
Total plate count	5	2	1,000	5,000	MML 1080
Yeasts	5	2	10	50	MML 1082
Molds	5	2	10	50	MML 1082
Staph. Aureus (coag+)	5	0	0	10	MML 1081
Coliforms	5	2	0	10	MML 1083
E. Coli	5	0	0	0	MML 1083
Salmonella	15	0	0	0	MML 1085

Packaging : Corrugated cardboard carton with a polyethylene liner

Shipping : Cases are stacked and stretch-wrapped on a non-returnable wooden pallet

Storage : Product must be shipped and stored at temperatures not exceeding 68°F/20°C

Vice President North America

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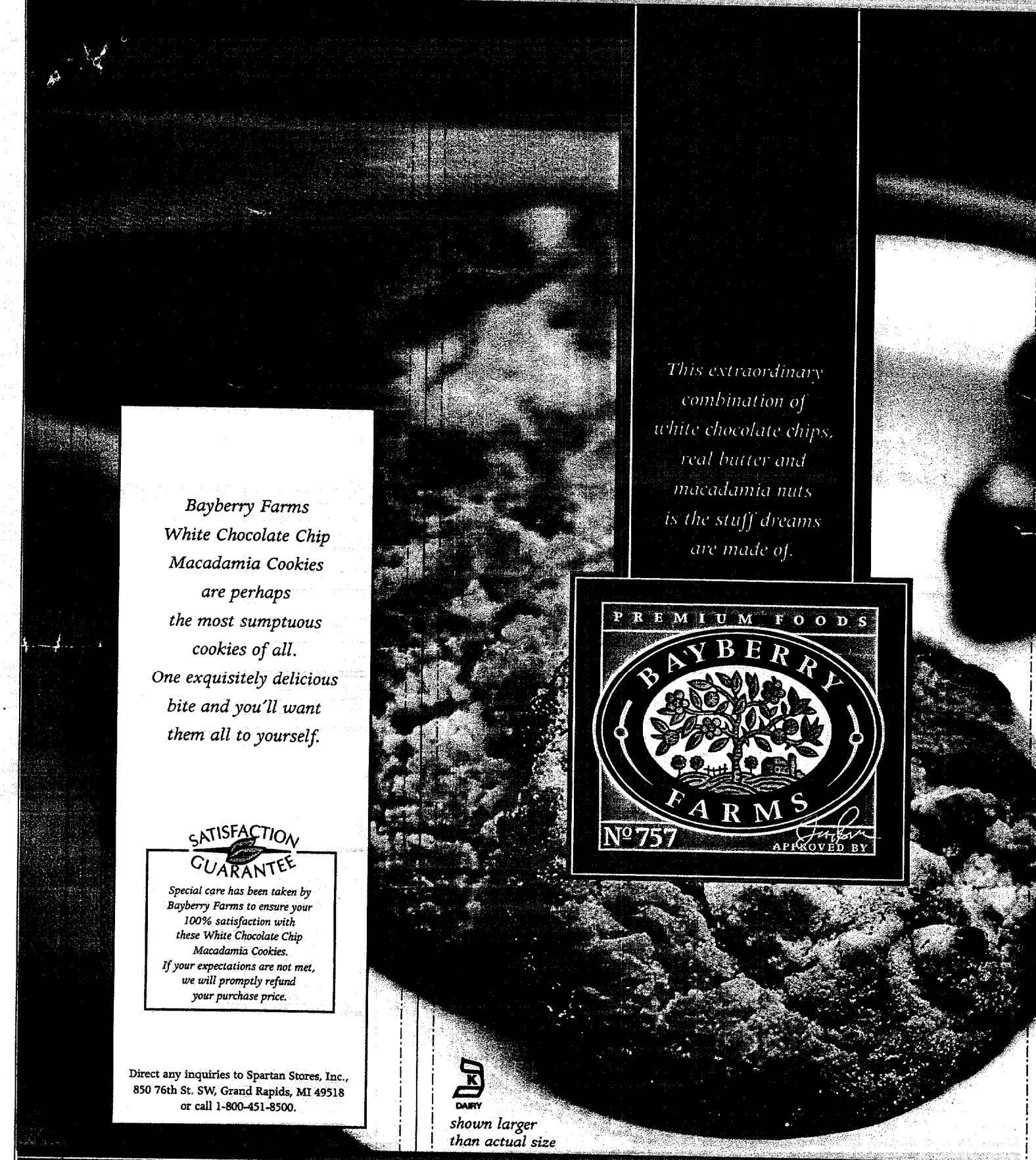
Rev: 00

Barry Callebaut Canada Inc.
B.P./P.O. Box 398 - 2950 rue Nelson street, Saint-Hyacinthe (Quebec) Canada J2S 1Y7
Tél.: (450) 774-9131 - Télécopieur: (450) 774-8335 / www.barry-callebaut.com



This extraordinary combination of white chocolate chips, real butter and macadamia nuts is the stuff dreams are made of.

Bayberry Farms White Chocolate Chip Macadamia Cookies are perhaps the most sumptuous cookies of all. One exquisitely delicious bite and you'll want them all to yourself.

SATISFACTION GUARANTEE

Special care has been taken by Bayberry Farms to ensure your 100% satisfaction with these White Chocolate Chip Macadamia Cookies. If your expectations are not met, we will promptly refund your purchase price.

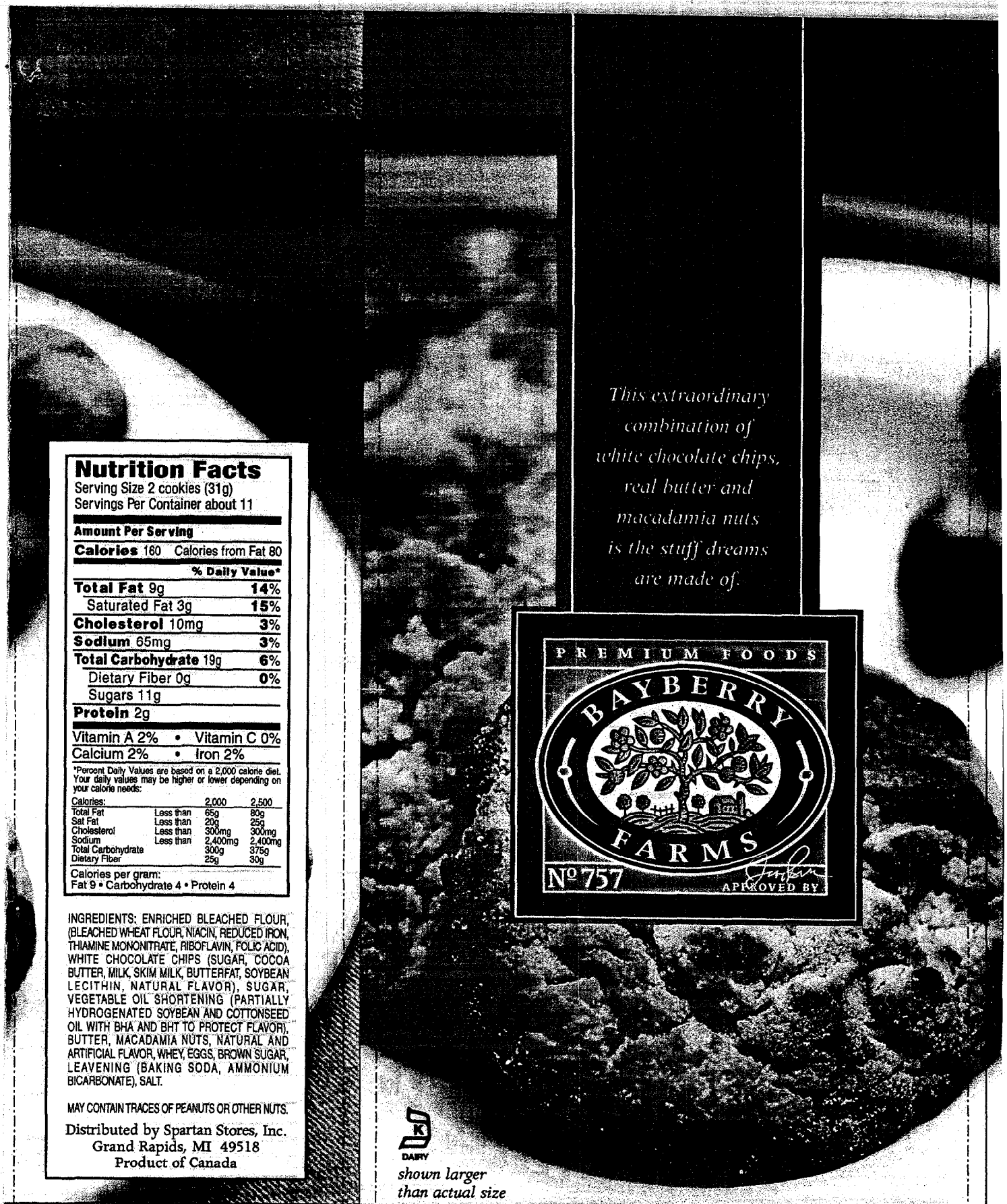
Direct any inquiries to Spartan Stores, Inc., 850 76th St. SW, Grand Rapids, MI 49518 or call 1-800-451-8500.

K DAIRY

shown larger than actual size

white chocolate chip MACADAMIA COOKIES

made with real butter



Nutrition Facts

Serving Size 2 cookies (31g)
Servings Per Container about 11

Amount Per Serving	
Calories 160	Calories from Fat 80
	% Daily Value*
Total Fat 9g	**14%**
Saturated Fat 3g	**15%**
Cholesterol 10mg	**3%**
Sodium 65mg	**3%**
Total Carbohydrate 19g	**6%**
Dietary Fiber 0g	**0%**
Sugars 11g	
Protein 2g	

Vitamin A 2%	• Vitamin C 0%
Calcium 2%	• Iron 2%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

Calories:		2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

INGREDIENTS: ENRICHED BLEACHED FLOUR, (BLEACHED WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE, RIBOFLAVIN, FOLIC ACID), WHITE CHOCOLATE CHIPS (SUGAR, COCOA BUTTER, MILK, SKIM MILK, BUTTERFAT, SOYBEAN LECITHIN, NATURAL FLAVOR), SUGAR, VEGETABLE OIL SHORTENING (PARTIALLY HYDROGENATED SOYBEAN AND COTTONSEED OIL WITH BHA AND BHT TO PROTECT FLAVOR), BUTTER, MACADAMIA NUTS, NATURAL AND ARTIFICIAL FLAVOR, WHEY, EGGS, BROWN SUGAR, LEAVENING (BAKING SODA, AMMONIUM BICARBONATE), SALT.

MAY CONTAIN TRACES OF PEANUTS OR OTHER NUTS.

Distributed by Spartan Stores, Inc.
Grand Rapids, MI 49518
Product of Canada

white chocolate chip MACADAMIA COOKIES

made with real butter